

# Complications from vaginally placed mesh in pelvic reconstructive surgery

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## Abstract

**Introduction and hypothesis** We describe complications associated with the use of transvaginal mesh for treatment of pelvic organ prolapse.

**Methods** We retrospectively identified patients referred to our institution from January 2003 through September 2007 who had complications after vaginal placement of mesh.

**Results** We identified 21 patients with a mean (SD) age of 61 (11) years. Types of mesh used included mesh kits ( $n=9$ , 43%), nontrocar mesh augmentation ( $n=5$ , 24%), IVS Tunneller ( $n=4$ , 19%), and unspecified ( $n=3$ , 14%). Eleven patients (52%) underwent more than one procedure before referral. Only three patients were referred by the original treating surgeon. Complications included mesh erosions in 12 women, dyspareunia in ten, and recurrent prolapse in nine. Sixteen patients (76%) were managed surgically. Follow-up survey among sexually active patients showed 50% with persistent dyspareunia.

**Conclusions** Use of vaginal mesh for pelvic reconstruction can produce complications. Multiple interventions may be necessary, and bothersome symptoms may persist.

**Keywords** Dyspareunia · Mesh erosion · Mesh kits · Minimally invasive · Recurrent prolapse

## Introduction

The use of synthetic materials in pelvic reconstructive surgery has been advocated as a way to improve surgical outcomes. Long-term results from more traditional repairs have been unsatisfactory [1, 2], and close to 30% of patients who have surgery for pelvic organ prolapse or urinary incontinence will need a repeat operation for recurrent prolapse or incontinence [3]. Use of transvaginal mesh has become increasingly popular despite the lack of prospective, long-term, controlled studies to justify the use of mesh over traditional repairs. Avoidance of native defective tissue, procedure simplification, decreased operating time, and decreased recurrence rates are among the proposed benefits of this technology.

Most of the experience with use of graft material in surgery comes from its applications in general surgery. Synthetic mesh has been used in the treatment of abdominal wall hernias with a low complication rate [4]. This has driven industry and pelvic reconstructive surgeons to adapt it for use in pelvic organ prolapse surgery. The use of synthetic mesh in pelvic reconstructive surgery is well established for sacrocolpopexy and for suburethral sling procedures, with excellent success and variable rates of morbidity [5].

Nonabsorbable mesh has been used in various forms and with various techniques for anterior and posterior compartment repairs with different rates of success and complications. One author reported his experience with using Marlex (CR Bard, Billerica, MA, USA) in the treatment of recurrent anterior vaginal wall prolapse and demonstrated a success rate of 100% at 1 year, but with an erosion rate of 25% [6]. Observational studies of the use of Atrium (Atrium Medical, Hudson, NH, USA) for vaginally augmented repairs showed prolapse recurrence of 6% and

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erosion rates of up to 19% [7, 8]. Several studies involving the use of Prolene (Johnson and Johnson, Somerville, NJ, USA) and Gynemesh (Gynecare, Somerville, NJ, USA) have been published [9]. These studies are largely retrospective case series, revealing recurrence rates of less than 10% and variable rates of mesh erosion and dyspareunia.

Options for repairing pelvic organ prolapse using vaginally placed mesh include fixed techniques or tension-free approaches, with or without trocar placement and with or without the use of insertion kits. This variability makes standardization of techniques and interpretation of the literature challenging. In recent years, “minimally invasive mesh trocar kits” for repair of pelvic organ prolapse have been granted US Food and Drug Administration approval. The techniques involve blind passage of trocars with a combination of transobturator anchoring for anterior support and sacrospinous ligament anchoring (via the ischiorectal fossa) for posterior and apical support. Four trocar systems are currently marketed in the US: Prolift (Gynecare, Somerville, NJ, USA), Perigee and Apogee (American Medical Systems, Minnetonka, MN, USA), and Avaulta (CR Bard, Covington, GA, USA). Although subject to the Food and Drug Administration 510K approval process, these surgical techniques have not been studied in randomized controlled trials. Recent observational case series with short-term follow-up have shown limited morbidity [10–12]; however, we and others [13] have observed an increasing number of complications, including complex mesh erosions, pain syndromes, recurrent prolapse, and dyspareunia, related to procedures using vaginally placed mesh to treat pelvic organ prolapse.

Here, we present our experience as a referral center treating patients with complications after procedures using vaginally placed mesh for reconstructive purposes. We describe the symptoms, physical findings, management, and outcomes in this cohort of patients.

## Materials and methods

We conducted a retrospective descriptive study of all women referred to the Urogynecology Division at Mayo Clinic in Rochester, MN, USA, from January 2003 through September 2007 with complications after procedures using vaginally placed mesh for pelvic reconstructive surgery. The authors do not perform these procedures, and all women were referred from outside institutions. The study was approved by the Mayo Clinic Institutional Review Board.

Study subjects were identified from our patient database by using diagnostic and procedural codes for the specified time frame. To isolate the desired cases for inclusion,

patients with a history of previous abdominal sacrocolpexy using mesh or placement of synthetic suburethral slings were excluded, unless these procedures were performed concomitantly with other vaginal reconstructive procedures using mesh. The medical records of patients identified who provided consent for research were reviewed by one of the authors (REB); data on demographics, medical and surgical history, presenting symptoms, physical findings, and subsequent management were collected. Using the Baden–Walker halfway system [14], we defined prolapse recurrence as the presence of grade 2 or greater pelvic organ prolapse at the time of initial referral.

All subjects were contacted for a follow-up telephone survey after surgical or medical intervention at our institution. The survey was conducted by two urogynecology fellows and included the completion of a condition-specific quality-of-life questionnaire (the Pelvic Floor Distress Inventory-Short Form 20) [15], an assessment of symptom improvement based on the Patient Global Impression of Improvement [16], and evaluation for dyspareunia. Dyspareunia was defined as a response of “sometimes,” “usually,” or “always” to the question “Do you feel pain during sexual intercourse?” (Pelvic Prolapse/Urinary Incontinence Sexual Function Questionnaire, question 5) [17], as previously described [18].

JMP 6.0.0 software (SAS Institute, Inc, Cary, NC, USA) was used to calculate descriptive statistics. Means, medians, and standard deviations were used for continuous data; numbers and percentages were used for categorical data.

## Results

Our search of the database identified 22 women who were referred to our department with complications after pelvic reconstructive surgical procedures using vaginally placed mesh. One patient refused authorization of use of her medical record for research and was excluded. Patient demographics are shown in Table 1. The group was primarily white and postmenopausal; the number of patients presenting increased sharply in the first 9 months of 2007.

All women had been treated surgically at outside institutions for symptomatic pelvic organ prolapse, and all had mesh placed vaginally during one or more of their pelvic reconstructive procedures. Table 2 shows the detailed surgical history of these patients before referral to Mayo Clinic. Fifteen patients (71%) underwent pelvic reconstructive procedures using vaginally placed mesh as a first operation for pelvic organ prolapse. Six patients (29%) had undergone failed traditional pelvic floor plication repairs before undergoing a mesh reconstruction. In nine women (43%), referral occurred after the first mesh-related surgery, whereas, in 11 women (52%), two to three

**Table 1** Baseline patient characteristics (*N*=21)

Variable	Value <sup>a</sup>
Age, year	61 (11)
White	19 (90)
BMI, kg/m <sup>2</sup>	24.5 (20.6–36.8)
Parity	3 (2–5)
Postmenopausal	18 (86)
Year of evaluation	
2003	0 (0)
2004	1 (5)
2005	3 (14)
2006	6 (29)
2007 (Jan–Sep)	11 (52)

BMI body mass index

<sup>a</sup> Values are mean (SD), no. (%), or median (range)

associated procedures had been performed before referral. One woman had six operations to address symptoms related to the initially placed vaginal mesh before referral. Overall, the median number of mesh-related surgeries before referral was two (range, one to six).

The original surgical procedure was performed by a general obstetrician–gynecologist in ten patients (48%), a urologist in nine (43%), and a urogynecologist in two (9%). Only three patients (14%) were referred by the original treating surgeon, whereas ten (48%) were referred by an alternate physician or health care provider and eight (38%) were self-referred.

Table 3 shows the presenting symptoms and physical findings of all patients at the time of evaluation at our institution. The most common patient symptom was dyspareunia (*n*=10). This was not associated with the number of pelvic floor surgeries before referral; the median number of surgeries was two (range, one to three) for patients with dyspareunia and one (range, one to six) for patients without dyspareunia. Other symptoms included chronic vaginal drainage in nine patients, pain not related to intercourse in seven, recurrent pelvic organ prolapse symptoms in seven, and urinary incontinence in ten.

Noteworthy findings on physical examination included vaginal shortening and narrowing in 48% of cases (Table 3, Fig. 1a). This was defined as a vaginal length of less than 7 cm and inability to freely place two finger breadths vaginally by the examining surgeon [19]. Twelve women (57%) had mesh erosions (Fig. 1b), four of whom had erosions at more than one site. Seven of these 12 patients had concomitant hysterectomy at the time of original mesh-implanting surgery. Nine women (43%) had evidence of recurrent prolapse of grade 2 or greater by the Baden–Walker halfway system [14], seven of which were

symptomatic. No infectious processes involving the mesh were seen in this series.

Treatment options were individualized to each patient. Sixteen patients (76%) opted for surgical management after conservative measures at other institutions and at ours had been exhausted. Table 4 describes the different surgical approaches taken at our institution. We defined complete vaginal mesh excision as the transvaginal removal of any visible or palpable mesh material from the anterior, posterior, or apical compartments. In the case of mesh kits, this excision was taken down to the origin of the mesh arms (ischiopubic ramus anteriorly and ischial spines posteriorly) whenever possible (Fig. 2).

For surgically managed patients, the mean (SD) operating time was 2.8 (1.4) h (95% confidence interval, 2.0–3.6 h), and the median estimated blood loss was 300 mL (range, 75–2,200 mL). The median (range) hospital stay was 3 (1–7) days. One intraoperative complication occurred during the course of a transvaginal mesh excision, which resulted in significant blood loss requiring blood transfusion, rectotomy with repair, temporary diverting loop ileostomy, and admission to the intensive care unit. A left ureterovaginal fistula developed in this patient, and she later underwent left ureteroneocystostomy after ureteral stent placement failed to resolve the situation. Four other patients required additional surgeries after the initial operation: one patient underwent reoperation for persistent pelvic pain and three patients had repeat surgeries for recurrent stress urinary incontinence. Our reoperation rate in this series was 31%.

Five patients (24%) opted for a conservative nonsurgical approach. One patient with dyspareunia and a foreshortened vagina chose to try vaginal dilators. After 4 weeks, she was able to resume sexual intercourse and reported feeling “a little better” based on the Global Impression of Improvement scale. Another patient who presented with persistent pelvic and abdominal pain after four pelvic floor operations was referred for physical therapy and chronic pain management. On her follow-up survey 5 months after therapy, she described feeling “much better.” Observation was the preferred course of action for a patient with prolapse and for another woman with chronic vaginal drainage and mesh erosion. For a patient with fecal urgency, prolapse, and vaginal mesh erosion, a trial of a pessary failed. However, this patient opted to treat her bowel symptoms first with a bowel regimen consisting of bulking agents and avoiding excessive straining before undergoing any further surgical procedures. Unfortunately, on her follow-up survey 8 weeks later, the patient reported feeling “much worse” because of her prolapse symptoms. At present, she has not scheduled a follow-up visit to discuss surgical repair.

**Table 2** Details of pelvic floor surgeries in 21 patients before referral

Patient no.	Surgery	First	Second	Third	Fourth	Fifth	Sixth
1	LAVH; Gynemesh bilateral SSL fixation; Gynemesh A&P repair; Gynemesh bilateral PVDR; TVT sling; cystoscopy		Gynemesh composite cystocele, rectocele, and enterocele repair (complex); IVS Tunneller bilateral SSL fixation (complex); bilateral mesh repair (complex)	Excision of eroded vaginal wall mesh; division of painful left uterosacral band (IVS Tunneller mesh, Gynemesh)	Excision of anterior Prolene mesh; revision of cystocele; cystoscopy	Removal of mesh from A&P vagina; cystotomy with repair; proctotomy with repair; cystoscopy; perineoplasty	Removal of vaginal mesh
2	TVT with repair of cystocele with polypropylene mesh augmentation; cystotomy with repair		Vaginal excision of eroded mesh				
3	IVS Tunneller; A&P repair; bone anchor sling with mesh anteriorly						
4	Vaginal hysterectomy with A&P repair, augmented with polypropylene mesh and vaginal vault repair with IVS Tunneller						
5	Laparoscopic bilateral PVDR and modified Burch urethropexy; bilateral round ligament plication, uterosacral plication, and posterior colpoperineorrhaphy with Pelvic graft		Anterior colporrhaphy with type I Prolene mesh augmentation	Transobturator sling with excision of eroded mesh; repeat anterior colporrhaphy with type I Prolene mesh and primary closure			
6	ASC with mesh		Abdominal exploration with resection of mesh	Apogee and Perigee repair			
7	Anterior colporrhaphy with mesh augmentation; posterior intravaginal slingplasty with IVS Tunneller; rectocele repair with mesh and transobturator sling		Repeat cystocele repair attaching Prolene sutures to the corners of the mesh				
8	Anterior repair with Perigee mesh kit; posterior and apical repair with Apogee mesh kit; SIS midurethral sling		Vaginal exploration, mobilization of vaginal "webbing"				
9	Apogee and Perigee cystocele and rectocele; Sparc sling placed		Tegress bulking procedure				
10	LAVH; BSO; vaginal vault suspension and rectocele repair with Prolift mesh kit; midurethral Monarc sling						
11	TVH; total Prolift repair for cystocele and rectocele; TVT Secur						
12	TVH; Prolift total mesh repair; TVT		TVT				
13	A&P repair; perineorrhaphy; DuraMatrix fascial graft reconstruction of anterior vaginal wall; TVT		A&P repair; uterosacral colposuspension; perineorrhaphy	Gynemesh bilateral SSL fixation; Gynemesh PS A&P repair with enterocele repair; Gynemesh PS bilateral PVDR; cystoscopy			
14	A&P repair with Prolift						

15	Gynemesh A&P mesh kit placement	Partial excision of vaginal mesh	
16	Apogee and Perigee A&P repair; Monarc sling		
17	TVH; BSO; Marlex mesh augmented anterior repair and transobturator sling		
18	TVH with posterior intravaginal sling for apical suspension and rectocele repair with Gynemesh	Transvaginal excision of the left IVS Tunneller and uterosacral ligament band and lysis of adhesions	Diagnostic laparoscopy and takedown of mesh transvaginally
19	LAVH; BSO; PVDH with Prolene mesh to secure bladder neck, midbladder, and proximal bladder to the Cooper ligament; posterior colpopneorraphy	Transvaginal anterior repair augmented with Gynemesh and Prolene suture	
20	TVH; BSO; bilateral SSL fixation; anterior colporrhaphy with Gynemesh; pubovaginal sling with Prolene mesh; posterior colporrhaphy		
21	Apogee and Perigee A&P repair		

*A&P* anterior and posterior, *ASC* abdominal sacrocolpopexy, *BSO* bilateral salpingo-oophorectomy, *IVS* intravaginal slingplasty, *LAVH* laparoscopic-assisted vaginal hysterectomy, *PVDH* paravaginal defect repair, *SSL* small intestine submucosa, *SSL* sacrospinous ligament, *TVH* total vaginal hysterectomy, *TVT* tension-free vaginal tape

All patients were surveyed by telephone as follow-up to their consultation and treatment. The survey was administered at a median of 7 months (range, 1–36 months) after surgery or last clinic visit in nonsurgically managed patients. No patients had sought care elsewhere or had undergone additional pelvic-floor-related procedures since their evaluation and treatment at our institution. The mean (SD) Pelvic Floor Distress Inventory-Short Form 20 score was 55 (43) out of a possible 300 points (with higher scores indicating higher degrees of distress); similar severities of symptoms were observed in the urinary, anorectal, and pelvic organ prolapse subscales. This patient group did not complete a condition-specific quality-of-life questionnaire at baseline, so score comparison could not be performed. The global impression of improvement scale indicated that six patients (29%) were “very much better,” five patients (24%) were “much better,” and four patients (19%) were “a little better.” Three patients (14%) replied that there was “no change” in their condition, and three patients (14%) indicated that their condition was “a little worse” or “much worse”; no patients reported being “very much worse.” One patient was not sexually active at baseline and was excluded from the follow-up sexual function assessment. Sixteen women (80%) had been sexually active since our intervention. The remaining four patients indicated lack of sexual activity owing to prolapse, partner’s health reasons, “fear of pain,” or still recovering from surgery. Among sexually active patients, the rate of dyspareunia remained 50%.

## Discussion

As the use of synthetic materials in pelvic reconstructive surgery increases, so do complications specific to their use. Although the incidence of these complications is unknown, our series demonstrates that, when they occur, multiple interventions may be required and bothersome and occasionally life-changing symptoms may persist. Several concerning trends emerged from our study. Over half the women evaluated for mesh-related complications presented in just the first 9 months of 2007, which suggests that as transvaginal mesh use becomes more widespread there will be an increase in mesh-related complications. Whether this reflects a learning curve for providers with less experience in pelvic reconstructive surgery, an inherent risk of synthetic mesh, or referral bias is not known. Furthermore, a notable number of patients in our series had persistent prolapse, contradicting previously published series on the use of vaginal mesh for the treatment of pelvic organ prolapse [7, 12, 20]. We recognize the limitations of not providing pelvic organ prolapse quantification data [21]. However, we used the Baden–Walker halfway system [14]



**Table 3** Presenting symptoms and physical findings at referral ( $N=21$ )

Symptom/finding	No. (%)
<b>Symptom</b>	
Dyspareunia ( $n=20$ ) <sup>a</sup>	10 (50)
Chronic vaginal drainage	9 (43)
Pain not related to intercourse	7 (33)
Pelvic organ prolapse symptoms (e.g., pelvic pressure/heaviness, bulge of tissue)	7 (33)
Stress urinary incontinence	6 (29)
Urinary urgency	6 (29)
Urge incontinence	4 (19)
Constipation	4 (19)
Vaginal bleeding/spotting	3 (14)
Urinary retention	3 (14)
Fecal urgency	2 (10)
<b>Finding</b>	
Vaginal pain on palpation	14 (67)
<b>Mesh erosion</b>	
Vaginal	11 (52)
Vesical	1 (5)
Urethral	1 (5)
Vaginal shortening	10 (48)
<b>Prolapse<sup>b</sup></b>	
Cystocele	5 (24)
Grade 2	2 (40)
Grade 3	2 (40)
Grade 4	1 (20)
Rectocele, grade 2	5 (24)
<b>Vault/uterine prolapse</b>	
Grade 2	3 (50)
Grade 3	3 (50)

<sup>a</sup> One patient not sexually active<sup>b</sup> Classification based on the Baden Walker halfway system

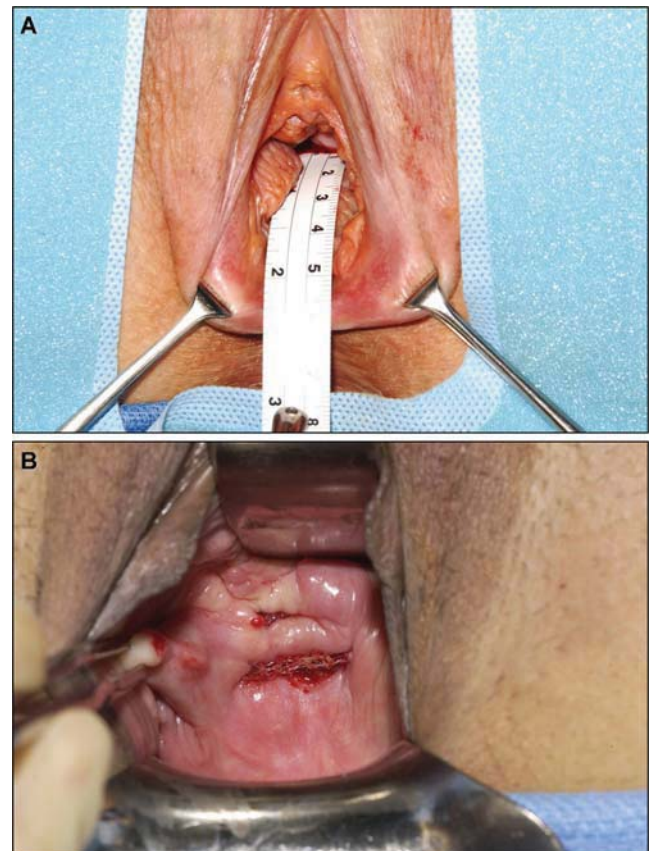
and observed that the vaginal apex is frequently involved, which questions the ability of these procedures to provide adequate level I support.

In a recent clinical trial, Hiltunen et al. [20] randomly assigned women with isolated anterior vaginal wall defects to receive a low-weight ( $38 \text{ g/m}^2$ ) self-tailored polypropylene mesh or traditional colporrhaphy. The mesh group had lower rates of recurrence (defined as point Ba $>-1$ ) at 1 year than the anterior colporrhaphy group. However, this trial excluded women with apical prolapse, incontinence, or significant posterior vaginal wall defects. Moreover, this trial did not use masked outcome assessment, suggesting measurement bias that could explain the observed differences.

Mesh erosions were among the most common findings in our series. Reported rates are as high as 25% [6, 22], with almost half of them being managed conservatively.

Even when a low-weight mesh was used, an 18% rate of mesh erosion was observed in one study, and some patients had persistent mesh erosion at 12 months [20]. Some studies with short-term follow-up have reported no incidence of mesh erosions [23, 24]. A series of 277 patients reported 34 “mesh exposures” (12.2%) at 2 months, 73% of which required surgical excision [25]. As with our cohort, concomitant hysterectomy was an associated risk factor for mesh erosion in that series, which has also been reported for abdominal sacrocolpopexy [26]. In our experience, most patients with mesh erosions required surgical treatment. Most erosions were complex, some of them in multiple sites, involving the bladder and urethra, causing sinus tract formation; more importantly, they were frequently associated with previous failed attempts at conservative treatment or partial excision at other facilities.

Dyspareunia after vaginal surgery is well described [19, 27]. Rates of dyspareunia as high as 26% have been reported after traditional posterior colporrhaphy, even when levator plication was not routinely performed [19]. Interestingly, a recent prospective study of 51 sexually active



**Fig. 1** Mesh related complications. **a** Notable vaginal shortening, with total vaginal length of 4 cm, in a 48 year old woman after vaginal hysterectomy, Prolift total pelvic floor repair, and tension free vaginal tape. **b** Extensive anterior vaginal wall mesh erosion in a 53 year old woman after pelvic floor repair using Perigee and Apogee

**Table 4** Surgical management at Mayo Clinic ( $n=16$ )

Surgical intervention	No. (%)
Complete vaginal mesh excision	12 (75)
Excision of eroded mesh from bladder/urethra	2 (13)
Anterior colporrhaphy	5 (31)
Posterior colporrhaphy	7 (44)
Vaginal vault prolapse repair	5 (31)
Abdominal sacrocolpopexy with mesh	3 (19)
Autologous rectus fascia sling	4 (25)
Synthetic midurethral sling	1 (6)

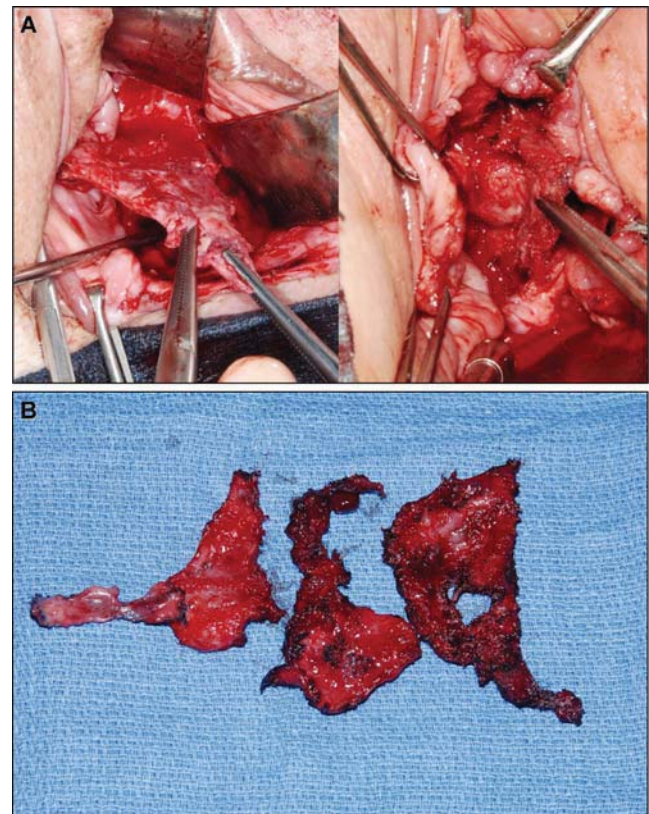
women who underwent vaginal surgery for prolapse and urinary incontinence showed no improvement in sexual function scores or sexual activity 6 months after surgery, despite anatomic and functional improvements. However, 25% of patients reported vaginal pain postoperatively [28].

Postoperative dyspareunia continues to be a difficult problem, and the use of graft materials in pelvic reconstruction may further complicate this issue. The incidence of de novo dyspareunia has been reported to be between 9% and 20% after anterior colporrhaphy mesh augmentation [7, 22, 29] and as high as 63% after rectocele mesh augmentation [11, 29]. Baessler et al. [13] reported substantial pain and dyspareunia for patients after anterior and posterior intravaginal slingplasty requiring surgical excision. In the present series, our interventions did not improve sexual function; the baseline rate of dyspareunia was 50%, which remained unchanged at follow-up.

One of our most important findings is that only 14% of patients were referred by the original surgeon, which suggests a lack of awareness of these complications by the original treating physician and the potential for under-reporting of the rate and extent of these complications due to nonrespondent/volunteer bias. Moreover, a urogynecologist was the original surgeon in only 9% of the cases. This supports the notion that surgical technique may contribute to the development of these complications and emphasizes the need for specialized training.

Our work has several limitations, such as its retrospective nature, small sample size, lack of homogenous interventions, variety of procedures and materials used, and lack of a meaningful denominator. Nevertheless, the common precedent of vaginally placed mesh makes this an interesting group to study. Given the geographic diversity of our referral practice, it is impossible to know the prevalence of these complications or the incidence on an annual basis. That, coupled with industry's reluctance to release specific sales volumes, makes this question much more difficult to answer.

As a major referral center, we continue to observe an increasing number of patients presenting to our practice for evaluation and management of similar complications. With the growing popularity of mesh insertion kits, in which a large surface area of synthetic material is placed [9], the vaginal surgeon is faced with the challenges of very complex surgical dissections. If mesh excision is warranted, tissue fibrosis, scarring, bleeding, and urinary tract and anorectal injury are easily encountered, which add to patient morbidity. In our experience, if dyspareunia and pain syndromes are the main complication and if palpable contractions and scarring are noted throughout the vagina, we favor the complete excision of the body of vaginal mesh, leaving the “arms” in place. In some instances, the combination of a vaginal and abdominal approach may be required. The only laparotomy we performed in this series was because of hemorrhage and for completing a diverting ileostomy after a rectal injury and repair. Patients must be fully aware of the potential risks of all surgical procedures, of the need, on occasion, for repeat interventions, and of the possible inability to achieve complete symptom resolution. It is important to remember that a percentage of patients who undergo pelvic reconstructive surgery with vaginally



**Fig. 2** Vaginal mesh excision. **a** Photographs demonstrate complete vaginal excision of fibrous tissue and synthetic mesh from a 48 year old patient. **b** Excised vaginal mesh from the same patient



placed mesh will have life-changing complications. Moreover, whereas minor complications such as small vaginal mesh erosions are simple and easy to manage, incapacitating pelvic pain, dyspareunia, and large-scale erosions can be exceedingly complex and not easily resolved.

We believe there is a role for mesh materials in pelvic reconstructive surgery. Their use in other areas of our practice, including sacrocolpopexy for vaginal vault prolapse and suburethral slings for stress urinary incontinence, has proven to be highly effective. However, we support the notion that the new minimally invasive total mesh repairs should be done in the context of clinical trials, in which patients receive adequate informed consent and outcomes are carefully monitored. When complications arise, multiple surgeries to address them may be required; substantial morbidity may ensue, and the patient's quality of life may be greatly affected. The widespread marketing of these technologies should be avoided until level I evidence becomes available demonstrating their superiority over traditional repairs, with acceptable rates of morbidity.

The questions of what degree of training is sufficient and who should be performing these types of procedures remain highly debated. We have developed an ongoing registry to prospectively collect data on these affected patients. In addition, the creation of a more optimally used national database should be established to allow patients and providers the opportunity to report mesh-related complications. This, along with data from ongoing trials, will begin to provide the necessary data to adequately study the mechanisms that contribute to efficacy and affect morbidity. Practitioners are compelled to answer these questions for the integrity of our profession as well as for the benefit of our patients.

**Conflict of interest** John B. Gebhart, MD, has grant/research support from CR Bard, Inc.

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